A Dissertation on

"COMPARISON OF LMA FASTRACH AND I-GEL AS A CONDUIT FOR BLIND TRACHEAL INTUBATION"

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DECLARATION

I, **Dr. N. ANURADHA**, Solemnly declare that the dissertation, titled "**Comparison of LMA Fastrach and I-GEL as a conduit for blind tracheal intubation"**, is a bonafide work done by me during the period of January 2010 to October 2010 at Government Stanley Medical College and Hospital, Chennai under the expert guidance and supervision of Dr. **R**. **SUBRAMANIYA BHARATHIYAR,** M.D, D.A. Professor and Head, Department Of Anaesthesiology, Government Stanley Medical College, Chennai.

This thesis is submitted to The Tamil Nadu Dr. M.G.R. Medical University in partial fulfilment of the rules and regulations for the M.D. degree examinations in Anaesthesiology to be held in April 2011.

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CERTIFICATE

This is to certify that the dissertation entitled "**Comparison of LMA Fastrach and I-GEL as a conduit for blind tracheal intubation**" is a genuine work done by **Dr. N. ANURADHA** for the partial fulfilment of the requirements for M.D. (Anaesthesiology) Examination of The TamilNadu Dr. M.G.R. Medical University to be held in April 2011, under my supervision and the guidance of **Dr. R. LAKSHMI**, Professor, Department of Anaesthesiology at Stanley Medical College, Chennai.

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COMPARISON OF LMA FASTRACH AND I-GEL AS A CONDUIT FOR BLIND TRACHEAL INTUBATION

INTRODUCTION

The major responsibility of the anaesthesiologist is to provide adequate ventilation to the patient. The most vital element in providing functional respiration is the airway.

Management of the airway has come a long way since the development of endotracheal intubation by Macewen in 1880 to present day use of modern and sophisticated airway devices.[1]

Using an endotracheal tube to secure a patient's airway is still the gold standard. Most routine orotracheal or nasotracheal intubations are performed with the help of a laryngoscope that has a curved or straight blade.

Difficulties encountered during intubation can be due to a number of factors and may be difficult to predict. It is important to have a strategy prepared and to be familiar with the equipment. This will help to avoid potential morbidity or mortality from the sequelae of hypoxia and/or cardiovascular catastrophe that may result from a failed intubation.

The anaesthesiologist must be familiar with the major decision making components of the difficult airway algorithm. Over the years many attempts have been made to address various factors responsible for difficult intubations and this has resulted in a number of different techniques. It is best to use affordable, safe and useful adjuncts that are best suited to our particular anaesthetic set up.

Insertion of a supraglottic device in these situations is a recognised alternative and may be a life-saving procedure. Some supraglottic devices allow for subsequent tracheal intubation using a blind or a fibreoptic technique. Tracheal intubation through a classical laryngeal mask airway had been extensively studied and is more time consuming.[3 – 5]

One device commonly used as a conduit for intubation is the intubating laryngeal mask airway (ILMA).[2] The ILMA has been the "gold standard" among the supraglottic airway devices since 1997. It has showed a high success rate for blind or fibreoptic-guided tracheal intubation in patients with both expected and unexpected difficult airways. [6– 10]

I-GEL supraglottic airway (Intersurgical Ltd., Wokingham, UK) is a relatively new device for airway management. It is made from Styrene Ethylene Butadiene Styrene and is anatomically preformed to mirror the peri-laryngeal structures. It can be described as an uncuffed peri-laryngeal sealer according to Miller's classification .[11]

We chose the I-GEL airway in comparison with the ILMA mainly because both devices allow direct tracheal intubation. I-GEL airway has some potential benefits over the ILMA: it is disposable, cheap and has an additional channel for drainage of gastric contents. Moreover, insertion of the I-GEL is usually easy and quick .[12]

Furthermore, its wide bore facilitates direct passage of a standard size tracheal tube. It can be a useful adjunct to tracheal intubation in patients with difficult airway as documented in several case reports.[13, 14] Data for the I-GEL airway as a conduit for blind endotracheal intubation is not available as only case reports have been published.

Hence a prospective randomized single blind study was designed to compare the new supraglottic airway device, I-GEL, to ILMA as a conduit for blind endotracheal intubation in patients undergoing elective surgery under general anaesthesia.

AIM OF THE STUDY

The aim of the study is to compare two supraglottic airway devices: I-GEL and Intubating LMA as a conduit for blind endotracheal intubation in patients undergoing elective surgery under general anaesthesia. We compare the two devices on the following metrics:

1) First attempt success rate for blind endotracheal intubation through the supraglottic airway device.

2) Total time required for the successful blind endotracheal intubation through the supraglottic airway device.

3) Ease of placement of supraglottic airway device

    a) Number of attempts required for the placement of the supraglottic airway device

    b) Time required for the placement of the supraglottic airway device.

I-GEL

The I-GEL airway is a novel and innovative supraglottic airway management device, made of a medical grade thermoplastic elastomer, Styrene Ethylene Butadiene Styrene, which is soft, gel-like and transparent. The I-GEL is a truly anatomical device designed to create a non-inflatable anatomical seal of the pharyngeal, laryngeal and peri-laryngeal structures while avoiding the compression trauma that can occur with inflatable supraglottic airway devices.

Figure 1: The I-GEL Device

I-GEL has several potential advantages including (a) easier insertion, (b) minimal risk of tissue compression, (c) stability after insertion (i.e. no position change with cuff inflation), and (d) latex free, sterile, single patient use device.

The buccal cavity stabiliser provides good vertical stability and axial strength upon insertion. It houses a standard airway channel and a separate gastric channel. It is not necessary to insert fingers into the mouth of the patient for achieving full insertion.[15]

An integrated gastric channel can provide an early indication of regurgitation, facilitates venting of gas from the stomach and allows for the passing of a naso-gastric tube to empty the stomach contents.

Figure 2: Interior of the I-GEL Device

COMPONENTS OF I-GEL

Soft non-inflatable cuff

The novel soft non-inflatable cuff fits snugly onto the perilaryngeal framework, mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossae, peri-thyroid, peri-cricoid, posterior cartilages and spaces. Each receives an impression fit, thus supporting the seal by enveloping the laryngeal inlet. The tip lies in the proximal opening of the oesophagus, isolating the oesophageal opening from the laryngeal inlet. The outer cuff shape ensures that the blood flow to the laryngeal and perilaryngeal framework is maintained and helps to reduce the possibility of neurovascular compression.

Gastric channel

The gastric channel runs through the device from its proximal opening at the side of the flat connector wing to the distal tip of the non-inflatable cuff. Since the distal tip of the device fits snugly and anatomically correctly into the upper oesophageal opening, the distal opening of the gastric channel allows for the passing of a nasogastric tube to empty the stomach contents and can facilitate the venting of gas from the stomach.

Epiglottic rest

An artificial epiglottis and a protective ridge help to prevent the epiglottis from down-folding or obstructing the distal opening of the airway. The epiglottic ridge at the proximal end of the bowl rests at the base of the tongue, thus keeping the device from moving upwards out of position and the tip from moving out of the upper oesophagus.

Buccal cavity stabiliser

The buccal cavity stabiliser has a built-in natural curvature and an inherent propensity to adapt its shape to the oropharyngeal curvature of the patient. It is anatomically widened and concaved to eliminate the potential for rotation, thereby reducing the risk of malposition. It also provides vertical strength to aid insertion.

SIZE SELECTION[15]

I-GEL	MAX SIZE OF CETT	NASOGASTRIC TUBE	WEIGHT
Size 3	6.0 mm	12G	30-60 kg
Size 4	7.0 mm	12G	50-90 kg
Size 5	8.0 mm	14G	> 90 kg

Table 1: Various sizes for the I-GEL

INDICATIONS

1. Securing a clear airway in difficult or unexpectedly difficult intubations in airway management of an anaesthetised patient.

2. In a known difficult or unexpectedly difficult intubation, for intubating the patient, by passing an endotracheal tube (ETT) through the device under fibre-optic guidance.

3. In a difficult or unexpectedly difficult intubation, to pass a gum-elastic bougie blindly, but gently, through the device whilst in-situ, into the trachea and to rail-road the ETT over it.

4. Use by the ambulance crew in difficult or unexpectedly difficult intubations in a pre-hospital setting in order to quickly establish and maintain a clear airway.

CONTRA-INDICATIONS

1. Non-fasting patients for routine and emergency anaesthetic procedures.

2. Trismus, limited mouth opening, pharyngeal or perilaryngeal abscess, trauma or mass.

3. Peak airway pressure of ventilation is not allowed to exceed 40cm H2O.

4. Patients with any condition which may increase the risk of a full stomach e.g. hiatus hernia, sepsis, morbid obesity, pregnancy or a history of upper gastro-intestinal surgery etc.

TECHNIQUE OF INSERTION

The lubricated I-GEL is firmly grasped along the integral bite block and the device is positioned so that the I-GEL cuff outlet is facing towards the chin of the patient. The patient is positioned in the '*sniffing the morning air*' position with head extended and neck flexed. The chin is gently pressed down before proceeding to insert I-GEL.

The leading soft tip is introduced into the mouth of the patient in a direction towards the hard palate. The device is glided downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance is felt. After connecting the circuit to I-GEL, appropriate placement and ventilation is determined by the chest wall movement, auscultation of breath sounds, a square-wave capnograph trace and no oropharyngeal leak.

Excessive force is not applied on the device during insertion. It is not necessary to insert fingers or thumbs into the patient's mouth during the process of inserting the device.

If there is early resistance during insertion, ‘Jaw thrust’, ‘Insertion with deep rotation’, or Triple manoeuvre is tried. After insertion, the tip of the airway is located into the upper oesophageal opening and the cuff is located against the laryngeal framework.

An appropriate size endotracheal tube is lubricated and inserted through the I-GEL. When the endotracheal tube advances smoothly with no resistance, the endotracheal tube cuff is inflated. The endotracheal tube adaptor is then attached and the endotracheal tube position is confirmed by capnograph.

The IGEL is removed using a stabilizing rod, after removing the 15mm endotracheal tube adaptor and grasping the endotracheal tube with fingers. The adaptor is reattached to the endotracheal tube, and the ventilation is resumed, and the endotracheal tube position is reconfirmed by capnograph. After confirming the endotracheal tube position, the tube is secured.

INTUBATING LMA

The classic Laryngeal Mask Airway (LMA) functions both as a ventilatory device and as an aid to blind/fibre-optic-guided tracheal intubation.

In 1983, while developing the LMA, Dr. A.I.J. Brain conducted a fibre-optic investigation that revealed the LMA's potential as a guide for endotracheal intubation.[16]

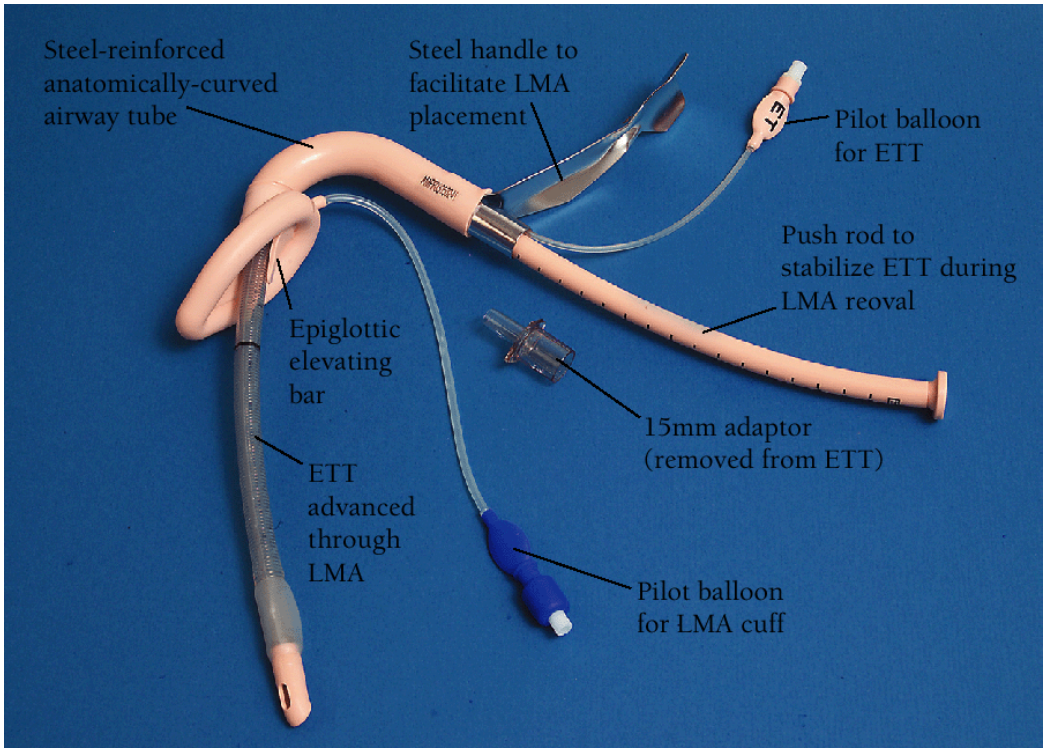

Figure 3: The ILMA Device

In response to clinicians' growing demands for a device that had the same ventilating properties as the classic LMA but would serve as a better conduit for intubation, he designed the Intubating Laryngeal Mask Airway (ILMA; LMA of North America, San Diego, CA) which was introduced in 1997. This device has better intubating characteristics than LMA and eliminates the head and neck manipulation and insertion of fingers inside the mouth during placement. [2]

The device has several features that distinguish it from the classic laryngeal mask airway device. The intubating laryngeal mask airway consists of a rigid, anatomically curved stainless steel tube 13 mm in internal diameter that is connected firmly at its distal end to a soft mask that fits over the larynx.

The angle of the metal shaft was carefully designed using measurements from sagittal MRI images, to fit well into the oral and pharyngeal space while keeping head and neck in neutral position.

Proximally the metal shaft forms a standard 15 mm connector for the anaesthesia circuit, and a rigid guiding handle serves both to insert the device, eliminating the need to insert fingers into the mouth and to stabilize and direct the device during intubation attempts.

In addition, the two bars at the aperture of the LMA classic have been replaced in ILMA by a single, movable epiglottic elevating bar that pushes epiglottis out of the way and allows smooth and unobstructed passage of the endotracheal tube as it emerges from the distal end of the ILMA's metal shaft.

This metal shaft can admit a flexible, reinforced endo-tracheal tube (ETT) specifically manufactured for this laryngeal mask. The device comes in three sizes for adults (3, 4, and 5), all of which can admit a range of ETT sizes, up to 8.0mm in diameter.

In addition, the shaft of ILMA is shorter than that of the LMA Classic, eliminating the need for longer endotracheal tube in patients with long neck.

SIZE SELECTION[17]

ILMA size	Patients' weight	Cuff volume	ETT size
3	30-50 kg	20 ml	6
4	50-70 Kg	30 ml	7
5	70-100 Kg	40 ml	8

Table 2: Various sizes for the ILMA device

TECHNIQUE OF INSERTION

The device is inserted with the patient's head and neck in neutral position[2] by using a single-handed operator technique. The lubricated tip of the fully deflated mask is placed behind the upper incisor teeth and the device is glided downwards and backwards along the hard palate with a continuous but gentle push to place it in the hypopharynx. The ILMA cuff is then inflated with air (Size 3: 20 ml; Size 4: 30 ml).[18]

After connecting the circuit to the ILMA, appropriate placement and ventilation were determined by the chest wall movement, auscultation of breath sounds, a square-wave capnograph trace, and no oropharyngeal leak.

The Endotracheal tube

The tracheal tube recommended by the manufacturer for use with the LMA-Fastrach is a silicone, wire-reinforced, cuffed tube with a tapered patient end and a blunt tip. This tube is flexible, which allows negotiation around the anatomical curves of the airway. It has a high pressure, low volume cuff that reduces resistance during intubation and makes cuff perforation as the tube passes through the ILMA less likely. The design prevents it from retaining the curvature that it assumes by passage through the shaft of the ILMA.[6] It is reusable and expensive.

The lubricated silicone endotracheal tube (7.0mm in females and 8.0mm in males) designed for blind intubation through the ILMA is passed. A transverse marker on the tracheal tube (15 cm) indicates the point at which it is about to emerge from under the epiglottic elevating bar.

The endotracheal tube has a longitudinal line, which should be oriented to face the patient's nose superiorly. Proper orientation of the longitudinal line causes the endotracheal tube to exit the ILMA at an angle that eases its passage into the trachea.

The endotracheal tube also has a circumferential line at a distance from the distal tip of the endotracheal tube that is equal to the length of the ILMA from the proximal to the distal port.

At the point where the circumferential line is advanced to the proximal port of the ILMA, the distal tip of the ETT will be in contact with the epiglottic elevator bar (which covers the distal port of the ILMA). The epiglottic elevator bar raises the epiglottis so that the ETT can enter the glottis unimpeded.

After confirmation of successful endotracheal intubation, the cuff of ILMA is deflated and the endotracheal tube connector removed. The ILMA is removed while the endotracheal tube is retained in place by the

tube stabilizer and the endotracheal tube is grasped with fingers when it is visible or palpable. The endotracheal tube connector is reattached and ventilation is resumed and the endotracheal tube position is reconfirmed by capnograph.

If resistance is felt, the tracheal tube is withdrawn to one cm beyond the epiglottis elevator bar. The following manoeuvres[2] were used:

1. ***Extension manoeuvre***

   Pulling the handle back towards the intubator.

2. ***Up-down manoeuvre***

   Withdrawal of ILMA by 5cm followed by reinsertion.

3. ***Optimization manoeuvre***

   Manual ventilation performed and position adjusted until optimal seal obtained.

4. ***Head–neck manoeuvre***

   Flexing of neck and extending the head (not in patients with cervical spine pathology)

5. ***Chandy manoeuvre***

   The ILMA is lifted slightly away from the posterior pharyngeal wall.

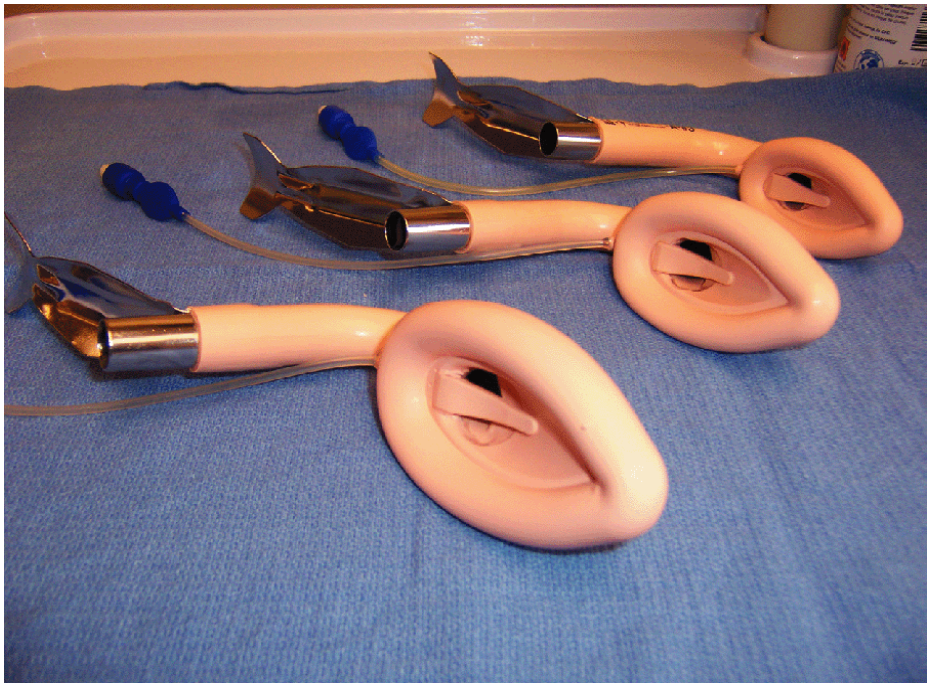

Figure 4: The ILMA Device

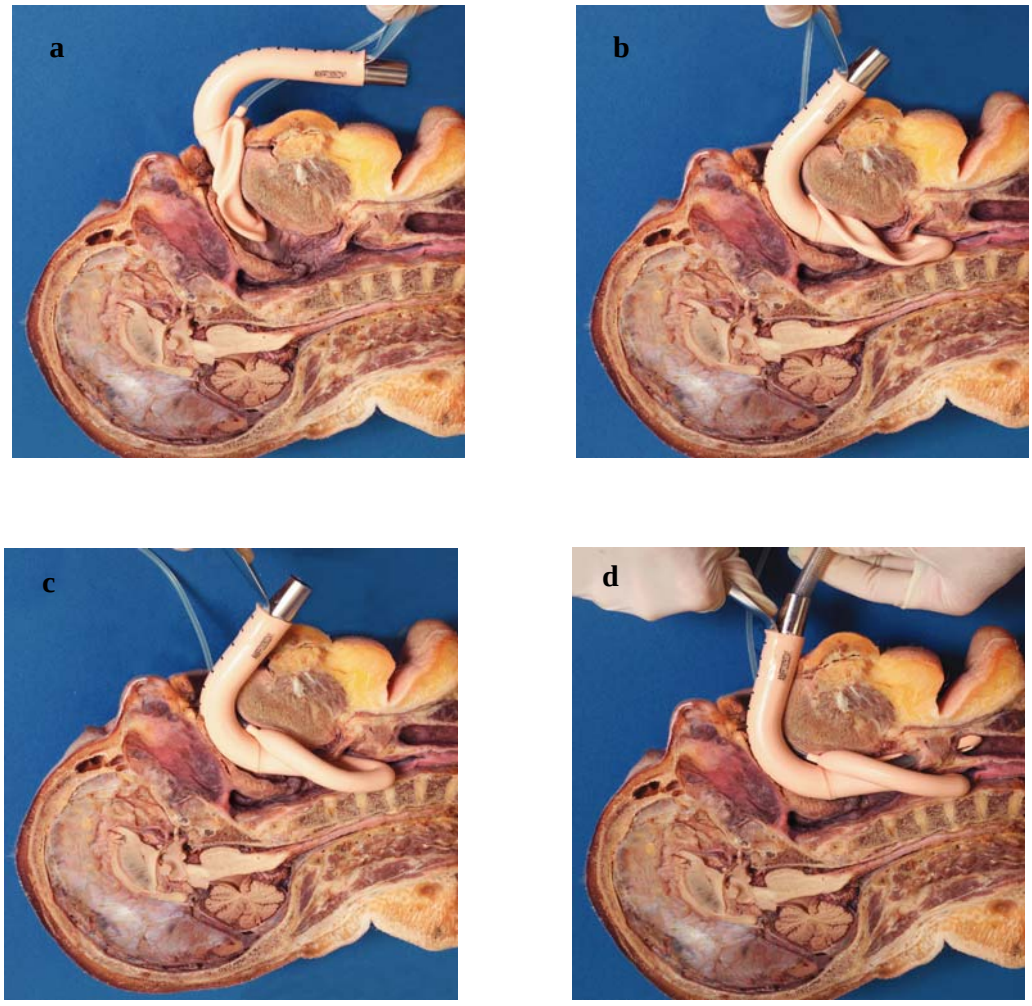

Figure 5: Insertion of the ILMA device and Endotracheal Intubation

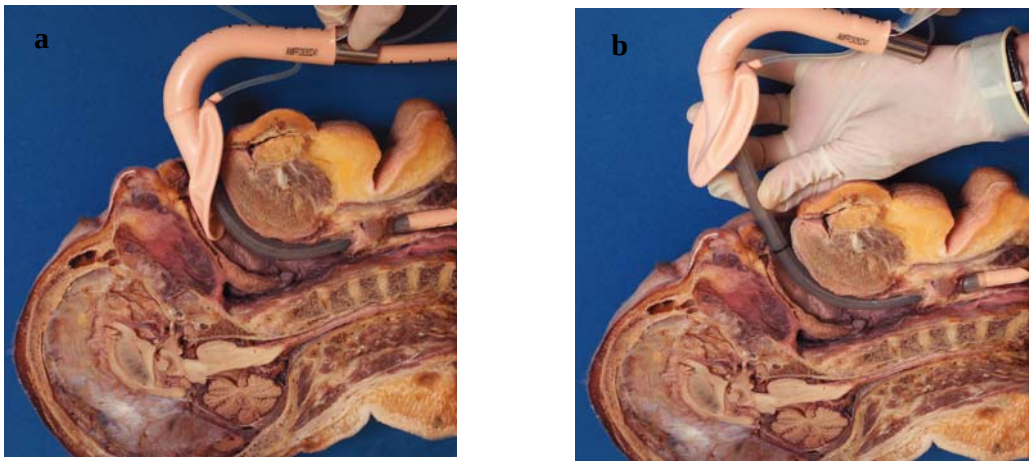

Figure 6: Removal of the ILMA Device with tube in situ

THE CHANDY MANOEUVRE

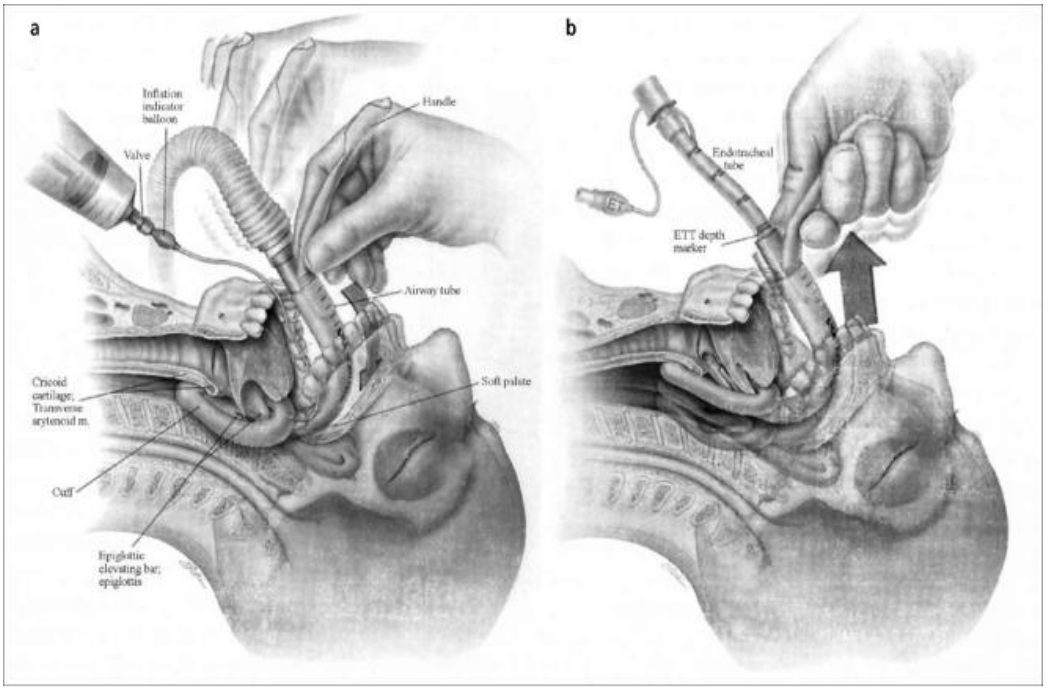

Figure 7: The Chandy manoeuvre

The Chandy manoeuvre was developed by Dr. Chandy Verghese and significantly improves the effectiveness of the ILMA. It incorporates two manoeuvres, which are performed sequentially, that improves lung ventilation and tracheal intubation using the ILMA.

1. The first step of the Chandy manoeuvre, which is important for establishing optimal ventilation, is to rotate the ILMA slightly in the sagittal plane using the metal handle until the least resistance to bag ventilation is achieved, while observing the patient's tidal volume and the capnographic waveform (if ventilation is being

controlled manually). This helps to align the internal aperture of the device with the glottic opening. However, if the patient is breathing spontaneously, an airway whistle (e.g., Patil intubation guide [Anesthesia Associates, San Marcos, CA]) can be attached to the proximal portion of the ILMA to optimize ventilation through it. Maximal whistling indicates optimal positioning of the ILMA.

2. The second part of the Chandy manoeuvre is performed just before blind intubation and consists of using the metal handle to lift slightly (but not tilted) the ILMA away from the posterior pharyngeal wall. This facilitates the smooth passage of the endotracheal tube into the trachea. This prevents the endotracheal tube from colliding with the arytenoids and facilitates the smooth passage of the endotracheal tube into the trachea.[16]

CONVENTIONAL PVC TUBES

The laryngeal mask airway (LMA)-Fastrach™ silicone wire-reinforced tube (FTST) was designed for tracheal intubation through the intubating LMA (ILMA). It is reusable and expensive.

The conventional polyvinyl chloride (PVC) tracheal tube is stiff and emerges from the ILMA with its distal end pointing too much to the anterior to have a chance of entry into the glottis.[9]

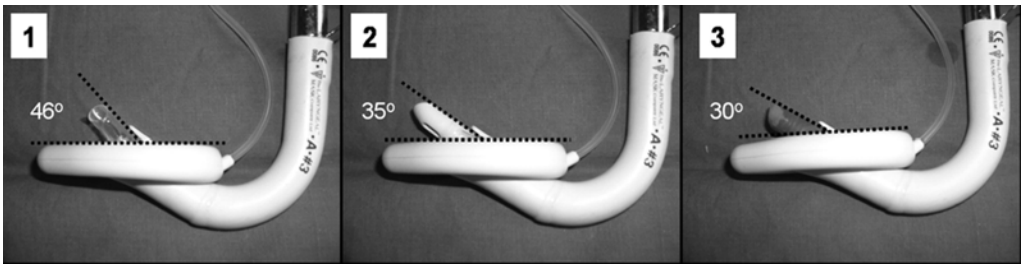

Figure 8: Comparison of emerging angle of FTST, PVC and LAT tubes

However, despite the cited advantages of the FTST, conventional PVC tubes are being used successfully for blind tracheal intubation through the ILMA.

The Rusch PVC tracheal tube (PVCT) is meant for single use and is much less expensive. Warming a plastic tube will result in success and complication rates similar to that of the tube from the LMA-Fastrach manufacturer.[19]

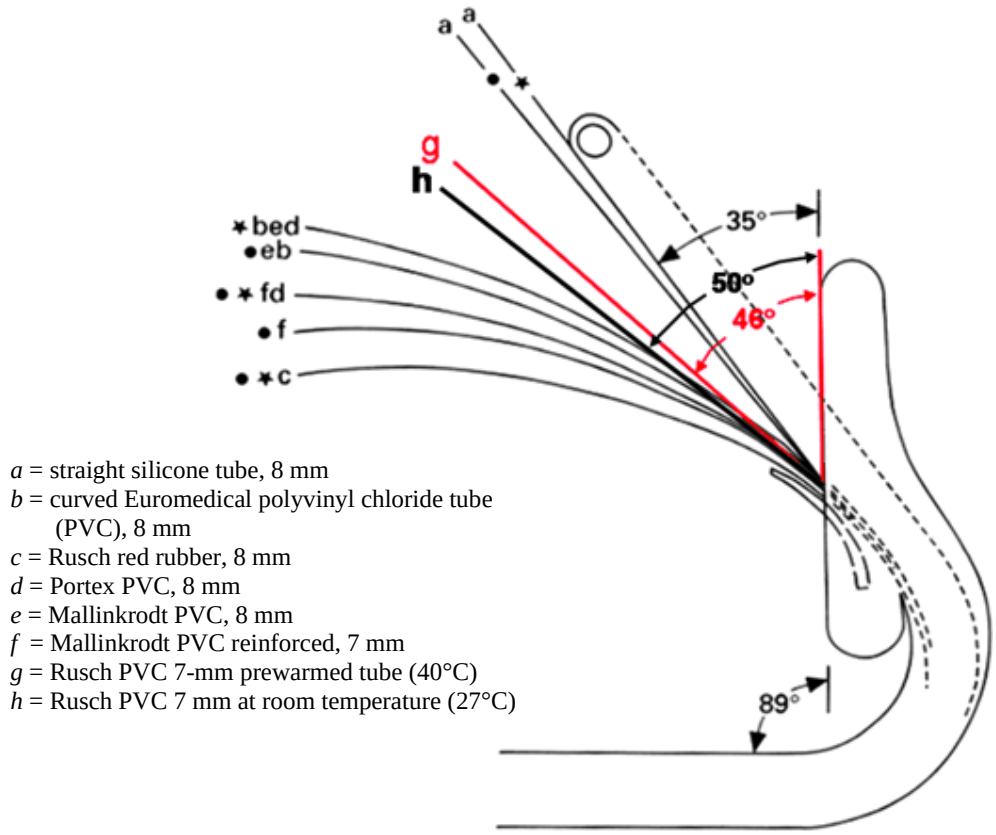

Figure 9: Effect of tracheal tube curvature for different tubes at 25°C (•) and 37°C (★) when passed through the intubating laryngeal mask airway.

While using the curved PVC tracheal tube, it may be helpful to orient the curve opposite the ILMA curve.[9, 20] Whatever the tracheal tube is used, it is essential that it is possible to remove the connector.[21] It is important to lubricate the tracheal tube well and pass it through the ILMA several times before use.[22]

The PVC tracheal tube is inserted with its natural curve along the ILMA curvature and in the reverse direction. As a result, the angle at which the tip of the tracheal tube emerged from the intubating LMA is 47° or 20°, respectively. [9, 20, 23]

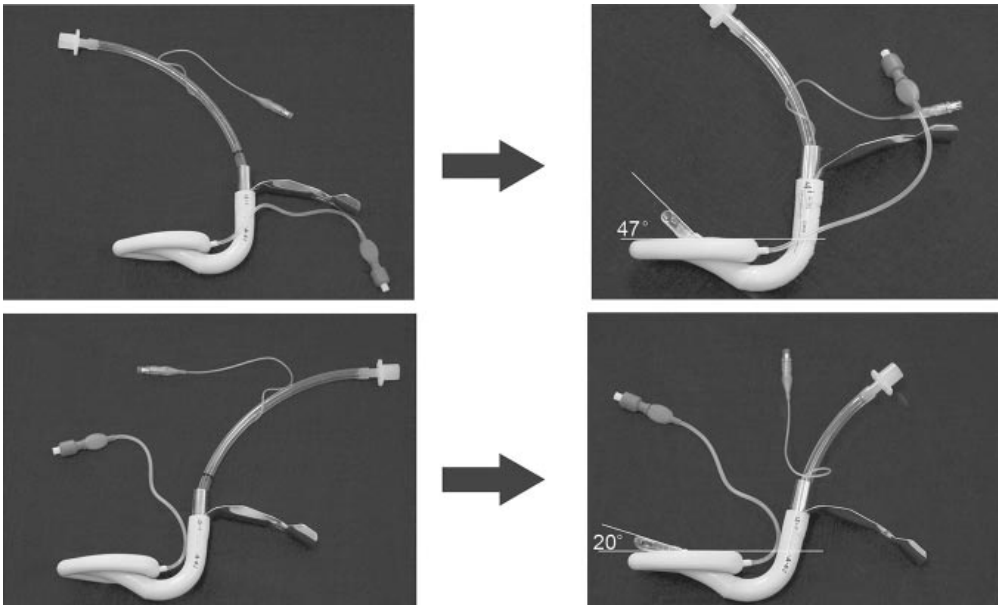

Figure 10: Comparison of emerging angle with orientation of the tracheal tube

REVIEW OF LITERATURE

P. Michaleka et. al.[24] (Resuscitation 2010; 81: 74–77)

Michaleka et. al. evaluated the success rate of blind intubation (using a gum-elastic bougie, an Aintree intubating catheter (AIC) and designated tracheal tube) and fiberscope guided tracheal intubation through the intubating laryngeal mask airway and the I-GEL supraglottic airway on three different airway manikins.

Twenty-five anaesthetists performed three intubations with each method on each of three manikins. The success rate of the fibre-optic guided technique was significantly higher than blind attempts ($P < 0.0001$) with both devices. For fibre-optic techniques, there was no difference found between the ILMA and I-GEL ($P > 0.05$). All blind techniques were significantly more successful in the ILMA group compared to the I-GEL ($P < 0.0001$). They concluded that, in manikins, fibre-optic intubation through both ILMA and I-GEL is a highly successful technique. Blind intubation through the I-GEL showed a low success rate and should not be attempted.

Dr. Neerja Bharti, Dr. Asit Kumar Naik[25] (Indian J Anaesthesia - 2006; 50(3): 205-208)

Dr. Bharti and Dr. Naik compared the ease of insertion and haemo-dynamic effects following tracheal intubation through intubating laryngeal mask airway (ILMA). Eighty adult patients undergoing elective surgery were randomly allocated into two equal-sized groups. Tracheal intubation was performed using either intubating laryngeal mask airway or Macintosh laryngoscope. Time to intubation was comparatively longer in ILMA group than laryngoscopy group. The overall intubation success rate was comparable among the groups. The changes in blood pressure were significantly less in ILMA group as compared to laryngoscope group ($p<0.05$). Their results suggested that ILMA offers advantage over laryngoscope in minimizing the haemodynamic effects to intubation. Therefore, it can be used as a suitable alternative to laryngoscopy for tracheal intubation.

Pankaj Kundra, Sujata N, Ravishankar M.[19] (Anesth Analg 2005;100:284–8)

They evaluated the success rate of blind tracheal intubation through the ILMA by using the Fastrach™ silicone wire-reinforced tube

(FTST), the Rusch polyvinyl chloride tube (PVCT), and the Rusch latex armoured tube (LAT). They divided 150 patients into three groups. FTST (n = 50), pre-warmed PVCT (n = 50), and LAT (n = 50) were used for tracheal intubation. Significantly more frequent success in tracheal intubation was achieved with the PVCT and FTST compared with the LAT. Tracheal intubation on the first attempt was similar with the PVCT and FTST (86%) and was significantly more frequent than with the LAT (52%) (P<0.05). Esophageal placement was significantly more frequent with the LAT when compared with the PVCT and FTST. The authors concluded that a pre-warmed PVCT can be used as successfully as the FTST for blind tracheal intubation through the ILMA, whereas the LAT was associated with more frequent failure and oesophageal intubation.

Tao Zhu, MD et al.[23] (Anaesthesia Analgesia 2007; 104: 213-214)

Dr. Zhu described insertion of Mallinckrodt polyvinyl chloride (PVC) endotracheal tubes into the intubating laryngeal mask airway (ILMA) with the curvature aligned with the ILMA versus rotated 180° from the intrinsic curvature of the ILMA. He found that the non-intuitive 180° rotation yielded a higher success rate, confirming previous findings of Joo and Rose. Since the emergence angle changed from 20° to 40° when mild force was applied, they suggested pre-

warming the endo-tracheal tube to render it more flexible and avoiding undue application of force. The rate of successful tracheal intubation was likely to increase, accompanied by a lower incidence of airway trauma and sore throat.

Ryu Komatsu et al.[26] (Br. J. Anaesth *2004; 93 (5): 655-659)*

They tested the hypothesis that the ILMA facilitates tracheal intubation even in patients wearing a rigid cervical collar. They performed blind tracheal intubation via an ILMA in 50 cervical spine surgery patients with a rigid Philadelphia collar in place and 50 general surgery patients under general anaesthesia. There were no significant differences between the collar and control patients in terms of total time required for intubation, number of intubation attempts, overall intubation success rate, or the incidence of intubation complications. Blind intubation through an ILMA was thus a reasonable strategy for controlling the airway in patients who are immobilized with a rigid cervical collar, especially when urgency precludes a fibre-optic approach.

A.N.Shetty et. al.[27] (The Internet Journal of Anesthesiology 2006; 10(2))

They performed blind endotracheal intubation through ILMA in 75 patients. In spite of 32% of patients having restricted and nil neck movements, ILMA was inserted in 76% and 20% patients in first attempt and second attempt respectively. They could successfully intubate through ILMA in 96% patients with 58% in the first attempt. Haemodynamic parameters were clinically not significant. They concluded that ILMA is a useful tool in patients with anticipated difficult airway especially in patients with cervical spine pathology and blind endotracheal intubation through ILMA was easy.

Theiler, Lorenz G. et. al.[28] (Anesthesiology 2009; 111 (1): 55-62)

This randomized controlled trial was performed in a simulated difficult airway scenario using an extrication collar limiting mouth opening and neck movement to compare the clinical performance of LMA-Supreme™ and I-GEL™. They concluded that both airway devices had similar insertion success and clinical performance in the simulated difficult airway situation. The authors found less epiglottic downfolding and better fibre-optic view but longer insertion time with the I-GEL™. Their study showed that both devices are feasible for emergency airway management in patients with reduced neck movement and limited mouth opening.

Hwan S. Joo and D. Keith Rose,[9] (Anesth Analg 1999; 88: 662–6)

They compared the blind and the fibre-optic tracheal intubation using the intubating laryngeal mask airway (ILMA). After a standardized inhaled anaesthesia induction protocol, tracheal intubation using ILMA with fibre-optic guidance (ILMA-FOB) and without fibre-optic guidance (ILMA-Blind) was compared with the control group of direct laryngoscopy (laryngoscopy group). For tracheal intubation, success rates were equal in all three groups. Total intubation time was longer for the ILMA-FOB group (77 s versus 48.5 s for laryngoscopy and 53.5 s for ILMA-Blind). They concluded that the success rate was equally high for tracheal intubation using ILMA-Blind and ILMA-FOB techniques. They stated that ILMA can be used as a primary airway for oxygenation and ventilation. Both methods of tracheal intubation using the ILMA were equally successful and suitable alternatives to laryngoscopy for tracheal intubation.

Pavel Michalek, MD, PhD, et al.[14] (Anesth Analg 2008; 106: 1501–4)

They described the successful fibre-optic-guided tracheal intubation through “I-GEL” airway in two uncooperative adult patients with genetic syndromes, learning disability, and predicted difficult

airway, scheduled for complex dental treatment under general anaesthesia. I-GEL maintained the airway immediately after induction, allowing oxygenation and ventilation. Location of the laryngeal inlet was successful on the first attempt with a fiberscope, and the tracheal tube was inserted into the trachea over the endoscope without complication in both patients. This report suggested another option for management of predicted difficult airways.

Gatward JJ.et.al [29] (Anaesthesia 2008; 63(10): 1124-30)

They studied the I- GEL in 100 elective, anaesthetised patients. First insertion attempt was successful in 86 patients, second attempt in 11 patients, and third attempt in three patients. Median insertion time was 15 s. On fibreoptic examination via the device, vocal cords were visible in 87 patients (91%). The I-GEL was easily and rapidly inserted, providing a reliable airway in over 90% of cases.

Sharma S, Rogers R, Popat M.[13](Anaesthesia 2007; 62: 412-423)

A teenage male patient was scheduled for closure of a colostomy. A size 4 IGEL airway was placed and ventilation was satisfactory. After confirmation of a good view of the vocal cords with a 4.1-mm adult fibreoscope, a size 6.5 mm cuffed tracheal tube was successfully passed through the stem of the IGEL blindly into the trachea at the first attempt. The IGEL was left in place until extubation.

L. de Lloyd et.al.[30] (Anaesthesia, 2010; 65: 36–43)

They compared the classic laryngeal mask airway and IGEL as adjuncts to fibrescope guided intubation in a manikin. They concluded that the IGEL was likely to be a more appropriate conduit than the classic laryngeal mask airway for fibrescope guided intubation.

R. M. Levitan [12](Anaesthesia 2005; 60: 1022–1026)

They studied the positioning and mechanics of IGEL in 65 non-embalmed cadavers with 73 endoscopies, 16 neck dissections, and six neck radiographs. A full view of the glottis (percentage of glottic opening score 100%) occurred in 44/73 insertions, whereas only 3/73 insertions had epiglottis-only views. Including the eight repeat insertions with a different size, a glottic opening score of > 50% was obtained in all 65 cadavers. The mean percentage of glottic opening score for the 73 insertions was 82%. In each of the neck dissections and radiographs, the bowl of the device covered the laryngeal inlet. They found that the I-GEL effectively conformed to the perilaryngeal anatomy despite the lack of an inflatable cuff and consistently achieved proper positioning for supraglottic ventilation.

MATERIALS AND METHODS

STUDY DESIGN

This study was a single blind, randomized, prospective comparative study conducted in Government Stanley Medical College and Hospital, Chennai.

STUDY SETTING AND POPULATION:

The Institutional Ethical committee approval was obtained before commencement of the study. Written informed consent was obtained from all the patients. Eighty adult patients of ASA Physical status 1& 2 of either sex undergoing elective surgical procedures under general anaesthesia were enrolled in the study.

The study was conducted at the General Surgery theatre complex, Stanley Medical College and Hospital, Chennai. The study was conducted from January 2010 to October 2010. The supraglottic airway device insertion and blind tracheal intubation was done by the author.

PATIENT SELECTION

Inclusion criteria:

- Age 20 to 50 years
- Both sexes
- Weight 40-70 kg.
- Mallampatti 1 & 2
- ASA physical status 1-2
- Patients undergoing elective surgery under general anaesthesia, requiring endotracheal intubation

Exclusion Criteria

- Patients with limited mouth opening (less than 2 cm)
- Anticipated difficult airway.
- Patients at increased risk of aspiration, or having a history of symptomatic gastro-esophageal reflux or hiatus hernia.
- Symptoms related to laryngo-pharyngeal anomaly.
- Musculoskeletal abnormalities affecting the cervical vertebrae.

MATERIALS:

- Intubating Laryngeal mask airway (ILMA)
- I-GEL
- Endo-tracheal tube
- IV cannulae,
- Monitors
- Drugs for general anaesthesia

STUDY METHOD:

After obtaining ethical committee approval, the patients were randomized into one of the two groups using a closed envelope method with predetermined group numbers and then single-blinded.

- Group A: I-GEL for airway management
- Group B: ILMA for airway management

Patients were advised for preoperative overnight fasting for 8 hours. They were given aspiration prophylaxis with Tab Ranitidine 150 mg and Tab Metoclopramide 10 mg on the night before surgery and Inj. Glycopyrrolate 5mcg/kg im, one hour before induction.

Standard monitoring was applied before induction and included ECG, pulse oximeter, capnography and Non-invasive Blood pressure monitor, temperature monitoring, neuromuscular monitoring.

Intravenous access was obtained with 18G peripheral venous cannula in the forearm. The patient was placed in supine position with the patient's head on a pillow of 10cms height.

Pre-oxygenation was done for 3 minutes with 100% oxygen. All patients were given Inj. Midazolam 0.02mg/kg iv, Inj. Fentanyl 2 mcg/kg iv. Anaesthesia was induced with Inj. Propofol 2mg/kg iv and Inj Atracrurium 0.5 mg /kg iv. The patients' lungs were manually ventilated by face mask with 2% Sevoflurane in oxygen for 3 minutes. An appropriate size supraglottic airway device was then inserted by the author.

Group A (I-GEL)

The patient was positioned in the 'sniffing the morning air' position with head extended and neck flexed. The chin was gently pressed down before proceeding to insert I-GEL.

The lubricated I-GEL was firmly grasped along the integral bite block and the leading soft tip was introduced into the mouth of the patient in a direction towards the hard palate.

The device was glided downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance was felt. After connecting the circuit to the IGEL, adequate placement of the device was confirmed with chest wall excursions, square wave capnography and no oropharyngeal leak. If there was early resistance during insertion, the following manoeuvres were tried: (a) Jaw thrust, (b) Insertion with deep rotation, and (c) Triple manoeuvre.

An appropriate size conventional PVC endotracheal tube was lubricated and inserted through IGEL with the endotracheal tube inserted backward, such that the concave bend was facing down. When the endotracheal tube was advanced smoothly with no resistance, the endotracheal tube cuff was inflated and ventilation confirmed by capnograph.

An intubation attempt was considered successful, if the tracheal tube was advanced smoothly without resistance and a positive capnographic tracing was obtained.

The 15mm endotracheal tube adaptor was removed. The I-GEL was removed after stabilising the tube using a stabilizing rod and by grasping the endotracheal tube with the fingers.

After attaching the adaptor to the endotracheal tube, the ventilation was resumed, and the endotracheal tube position was reconfirmed by chest wall movement, auscultation of breath sounds, a square-wave capnograph trace.

A “failed intubation attempt” was considered when tactile resistance was felt while advancing the tracheal tube or esophageal intubation.

The second attempt was made with the reinsertion of either the same or different size IGEL and after optimising ventilation, the tracheal intubation was attempted through the device.

Figure 11: Insertion Technique for I-GEL

Figure 12: Manoeuvre for Insertion of I-GEL

Group B (ILMA)

An ILMA was inserted into the hypopharynx with the head–neck in the neutral position, and the cuff was inflated with air up to the maximum recommended volume (20 ml in size 3 and 30 ml in size 4). Adequate ventilation was assessed by chest wall movement, capnograph waveform during manual ventilation.

If adequate ventilation was not attained, the ILMA was manipulated (Chandy's manoeuvre- step1) in situ. If the ventilation was not achieved in the first attempt, the same ILMA device was either reinserted or change of ILMA size was done during subsequent attempt and optimal ventilation was confirmed.

The point at which the tracheal tube is about to emerge from the epiglottic elevating bar was noted on the endotracheal tube before insertion. An appropriate size conventional PVC endotracheal tube (without 15mm connector) was inserted through ILMA with the endotracheal tube inserted backward, such that the concave bend was facing down.

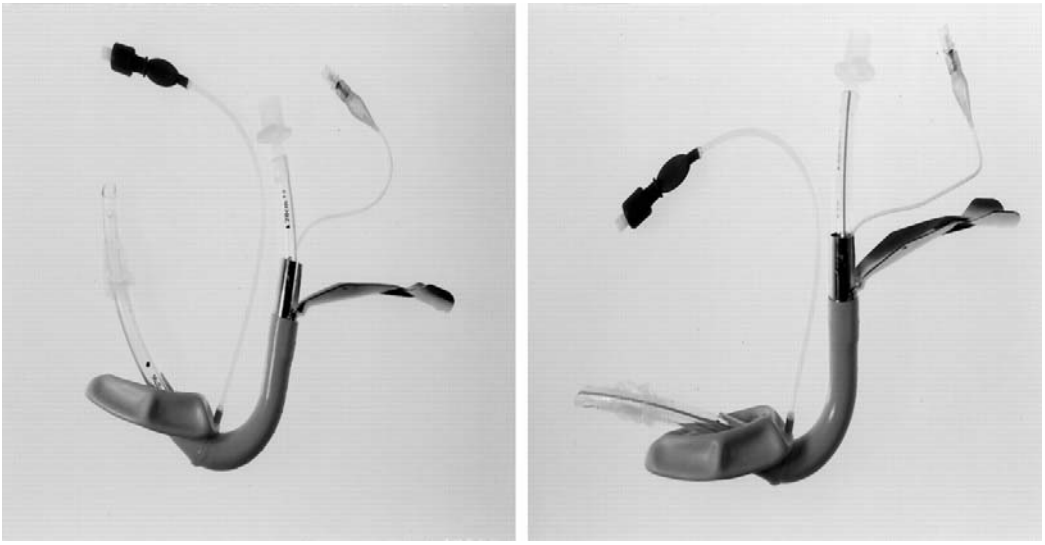

Figure 13: Effect of endotracheal tube curvature on intubation through ILMA

If resistance was encountered during passage of the tracheal tube, the tracheal tube is withdrawn to one cm beyond the epiglottic elevator bar and “Chandy’s manoeuvre step-2” was performed and further advancement of the tube was attempted.

An intubation attempt was considered successful, if the tracheal tube was advanced smoothly without resistance beyond 15cms and a positive capnographic tracing was obtained. The endotracheal tube adaptor was removed. The ILMA was then removed after deflating the cuff and stabilizing the endotracheal tube with the stabilizing rod and grasping the tube with fingers once visible. The endotracheal tube adaptor was reattached and ventilation was reconfirmed by capnography.

A “failed intubation attempt” was considered when (i) tactile resistance was still felt while advancing the tracheal tube despite the adjusting manoeuvres (ii) the tracheal tube was advanced the full distance, but no capnographic tracing was seen (esophageal intubation).

The second attempt was made with the reinsertion of either the same or different size ILMA and after optimising ventilation, the tracheal intubation was attempted through the device.

In both the groups, intubation through the supraglottic airway device was limited to two attempts. Intubation failure was recorded if, despite two attempts, repeated tactile resistance or esophageal intubation were encountered. When intubation was unsuccessful after two attempts, the procedure was abandoned, and tracheal intubation was performed under direct laryngoscopy.

Primary outcome measure was first attempt success rate for blind endotracheal intubation between IGEL and ILMA. Other outcome measures include total time required for tracheal intubation and ease of insertion of supraglottic airway device.

Ease of insertion of the supraglottic airway device would include number of attempts and time required for insertion of the device.

"Supraglottic Airway Device insertion time" was defined as the time from removal of the face mask to the time ventilation was established through the supraglottic airway device with CO_2 confirmation.

"Tracheal intubation time" was defined as the time from loss of CO_2 due to disconnection of the circuit from the supraglottic device to the time of reappearance of the CO_2 from the tracheal tube with no evidence of cuff leak with positive pressure ventilation.

Intubation failure was recorded if, despite two attempts, repeated tactile resistance or esophageal intubation were encountered. Patients with unsuccessful intubation were excluded from the analysis of total intubation time. Number of failed attempts at intubation was also noted

Ease of removal of supraglottic airway device after establishing tracheal intubation was noted by the time taken to remove the device (time from insertion of pusher to reconnection of breathing circuit to the tracheal tube). Any critical incident during device removal, such as accidental extubation or tube displacement was noted.

The heart rate and oxygen saturation were recorded continuously and blood pressure was recorded after induction,1 minute and 5 minutes after successful tracheal intubation and then at every 5 minutes till the end of surgery.

Any problem encountered during intubation was recorded. Complications such as saturation < 95%, dental trauma, esophageal intubation, laryngospasm, blood staining of the device (mucosal trauma), lip or dental injury were looked for.

OBSERVATION AND RESULTS

Eighty patients of either sex belonging to ASA PS 1 & 2, undergoing elective procedures under general anaesthesia were studied. The data were collected and analyzed with SPSS Version 15 (SPSS Inc., Chicago, IL).

Demographic data and the time taken for device placement, tracheal intubation and device removal among the groups were analyzed with unpaired t test. Chi-square analysis was used for comparing sex and the number of attempts required for intubation through the supraglottic device insertion.

Chi square analysis with Yates' continuity correction was applied to compare the number of attempts required for supraglottic device insertion and success and failure rate for intubation. Paired t test was used to compare the hemodynamic response at 1minute after intubation from the baseline values within the group. Unpaired t test was used to compare the hemodynamic response to intubation in between the groups. $p < 0.05$ was considered statistically significant.

AGE DISTRIBUTION:

GROUP	N	MEAN (Years)	S.D	p value
I-GEL	40	29.17	5.47	p=0.693
ILMA	40	28.65	6.33	

Table 3: Age distribution of patients in the two groups

The mean age in both the groups was around 29 years. Both groups were comparable with regard to age and there was no statistically significant difference between the two groups. (p=0.693)

WEIGHT DISTRIBUTION:

GROUP	N	MEAN (Kg)	S.D	Student's t- test p value
I-GEL	40	60.82	7.44	t =0.30
ILMA	40	60.77	7.62	p =0.976

Table 4: Weight Distribution

Both groups were comparable in terms of weight, the average weight being similar - around 60 kg in both groups. In both the groups, majority of the patients were in the range of 61-70 Kg. Six patients in the IGEL and five in the ILMA were in the range of 40-50 Kg.

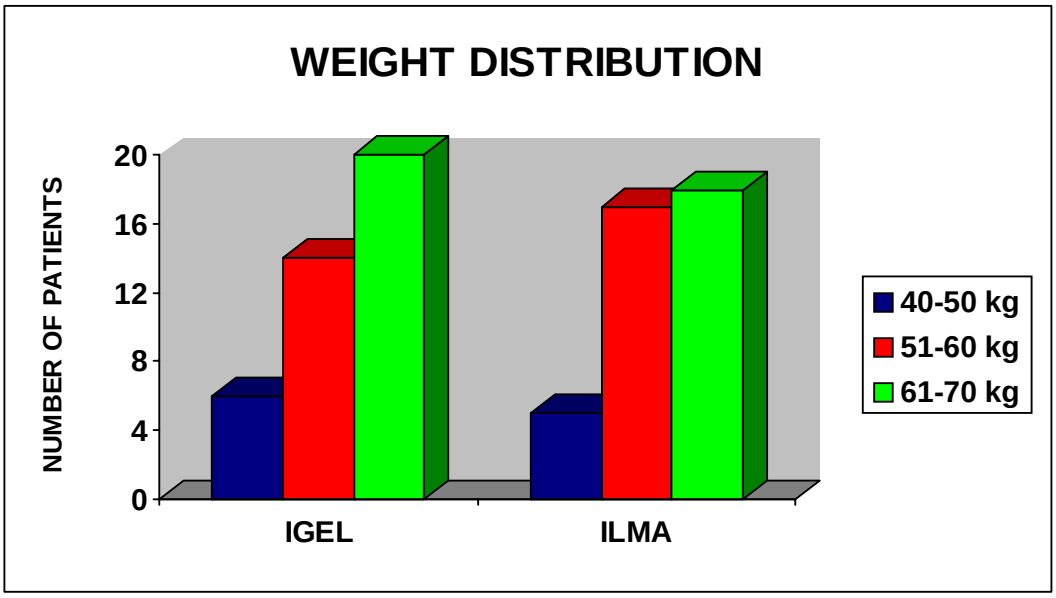

Figure- 14: Weight Distribution

COMPARISON OF SEX DISTRIBUTION

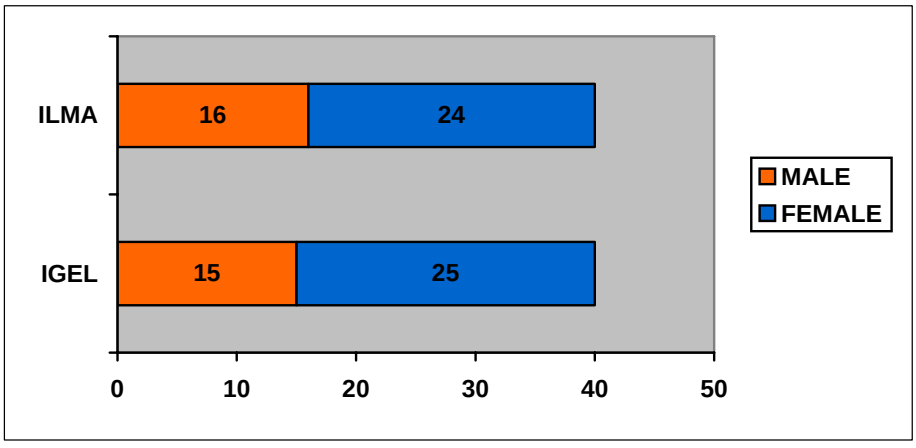

Figure-15: Sex distribution

In ILMA group, 16 were male and 24 were female. In IGEL group, 15 were male and 25 were female. No significant difference was found between the two groups in terms of gender distribution. Chi square analysis: $X^2 = 0.53$; p=0.818 (not significant).

SUPRAGLOTTIC AIRWAY DEVICE AND ENDOTRACHEAL TUBE SIZE

SIZE		I-GEL	ILMA	TOTAL
Device	**ETT (mm I.D.)**			
3	**6**	12	10	22
4	**7**	28	30	58
TOTAL		40	40	80

Table 5: Supraglottic device and ETT size used in both groups

The size of the supraglottic airway device used in both the groups in the study was 3 and 4. Size 4 was predominately used in both the groups, 30 patients in ILMA group and 28 in I-GEL group. Size 4 was used in patients with weight 50 – 70 Kg in ILMA group and 50-90 kg in IGEL group. In our study, most of the patients' weight was in the range of 50–70 Kg. The size 3 and 4 supraglottic airway devices accommodated 6 mm I.D and 7 mm I.D endotracheal tubes respectively.

SUPRAGLOTTIC DEVICE INSERTION TIME

GROUP	N	MEAN (SECONDS)	SD	P value
I-GEL	40	15.62	2.65	t =2.955 **p =0.004***
ILMA	40	17.17	1.98	

*** Statistically significant**

Table 6: Device insertion time (in seconds) for both groups

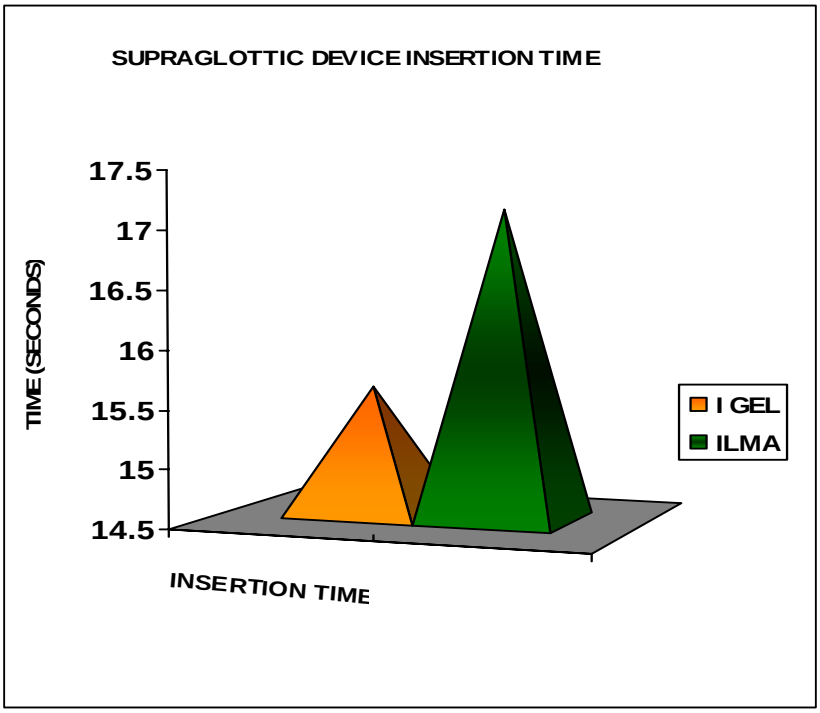

Figure – 16 Supraglottic Device Insertion Time

The least time required for I-GEL placement was 10 seconds in one patient versus 14 seconds in ILMA group. The maximum time required for a single attempt of placement of the device was 18 seconds

in I-GEL and 20 seconds in ILMA. The average time taken for the placement of I-GEL (15.62± 2.65 seconds) was significantly less when compared with ILMA (17.17 ±1.98 seconds). (P<0.05)

NUMBER OF ATTEMPTS FOR SUPRAGLOTTIC DEVICE INSERTION

GROUP	NO. OF ATTEMPTS		TOTAL	CHI-SQUARE YATES' CORRECTION
	1	2		
IGEL	36	4	40	X^2=0.180 p=0.671
	90%	10%	100%	
ILMA	38	2	40	
	95%	5%	100%	

Table 7: Number of attempts for supraglottic device insertion

Both the devices were placed successfully in the first attempt in 90% of patients in IGEL group and 95% of patients in ILMA group. Insertion and effective ventilation through both devices were possible in all cases in both the groups. In I-GEL group, in three patients, the size 4 device was replaced with size 3. In one patient the same device was repositioned with jaw thrust during second attempt. In patient with body weight in the range of 50 to 60 kg, I-GEL of size 3 and 4, both can be used, so the size selection was at the discretion of the anaesthesiologist.

In ILMA group, during second attempt, two patients required device repositioning and adjusting manoeuvre (Chandy manoeuvre: step 1) to achieve adequate ventilation. There was no significant difference between the two groups in the number of attempts for insertion of supraglottic airway device. (p= 0.671)

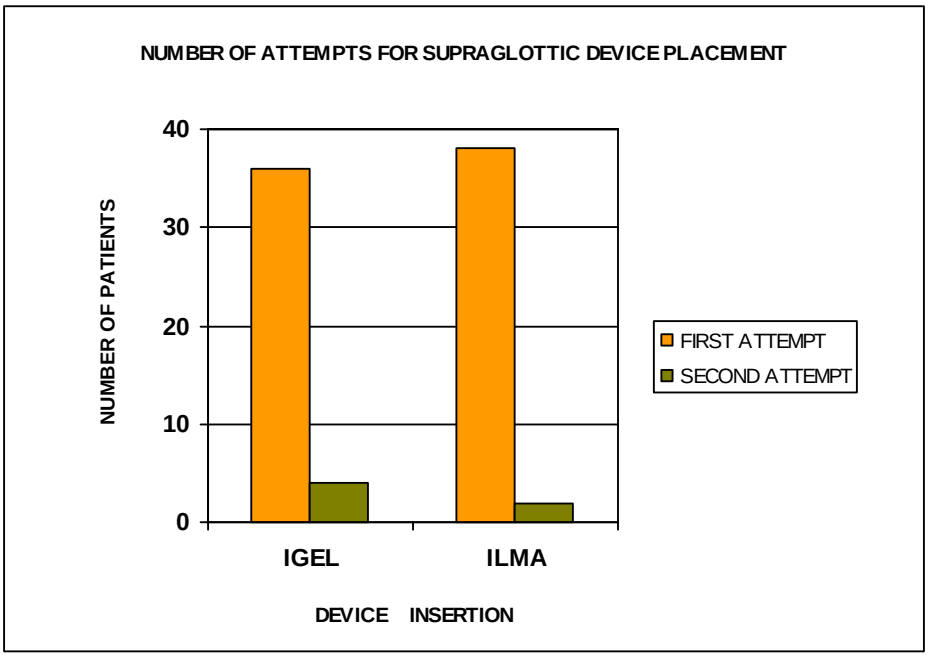

Figure 17: Attempts for supraglottic device placement

TIME FOR FIRST ATTEMPT TRACHEAL INTUBATION

GROUP	N	MEAN (seconds)	SD	Student's t-test p value
I-GEL	24	15.88	2.49	t =0.584 p =0.5611
ILMA	35	16.31	3.04	

Table 8: Time for First attempt Tracheal intubation

The mean time for successful first attempt tracheal intubation was 15.88 seconds and 16.31 seconds in I-GEL and ILMA group respectively. There was no statistical significant difference between the two groups.

NUMBER OF ATTEMPTS FOR SUCCESSFUL TRACHEAL INTUBATION

GROUP	NO.OF ATTEMPTS			TOTAL	CHI-SQUARE YATES' CORRECTION
	1	2	FAILURE		
IGEL	24	5	11	40	X^2=8.78 **p= 0.0124***
	60%	12.5%	27.5%	100%	
ILMA	35	3	2	40	
	87.5%	7.5%	5%	100%	

*** Statistically significant**

Table 9: Number of attempts for successful tracheal intubation

Among 35 patients who were intubated in first attempt, 28 didn't require any manoeuvre and 7 required Chandy manoeuvre step 2 just before intubation.

Three patients were intubated in second attempt in ILMA group despite adequate ventilation achieved through the device during the initial placement. In one patient, resistance to tube was observed at 2cms from the transverse mark, and down-folding of epiglottis might be a reason and hence the same device was reinserted with jaw thrust to prevent epigottic down-folding.

In the other two patients, esophageal intubation occurred in the first attempt and the size 4 was large and replaced with size 3 and both were intubated successfully in second attempt. Despite Chandy manoeuvres and reinsertion of device, repeated esophageal intubation was recorded in 2 patients in the ILMA group who were subsequently intubated successfully under direct laryngoscopy. Both of them had Cormack Lehane laryngeal view 1 under direct laryngoscopy.

Intubation was successful through the I-GEL in first attempt without any manoeuvre in 24 patients and second attempt in 5 patients. In two patients, oesophageal intubation occurred during the first attempt.

During second attempt, the device was removed and reinserted and intubated successfully. In two patients, tactile resistance was felt, and smaller size endotracheal tube was used for subsequent successful intubation. In another patient, size 4 was replaced with size 3 and subsequently intubated.

FIRST ATTEMPT SUCCESS RATE FOR TRACHEAL INTUBATION

First attempt success rate was high in ILMA group with 87.5% while only 60% in I-GEL group. Chi-square test: $x^2=7.813$; $p=0.005$. There was a statistical significant difference between the two groups. ($p<0.05$)

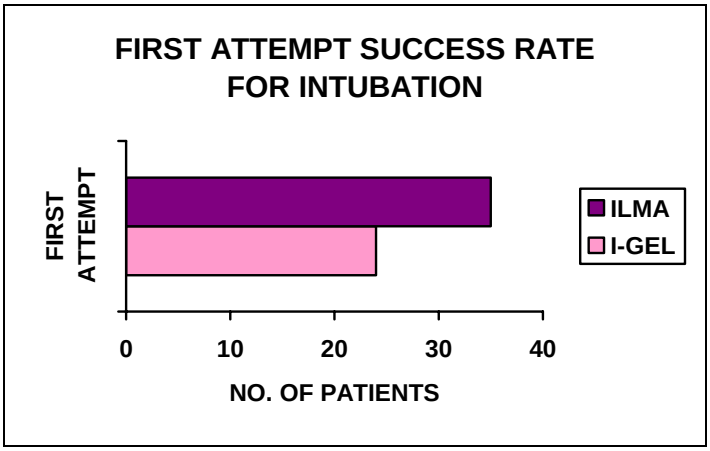

Figure-18: First attempt success rate for tracheal intubation

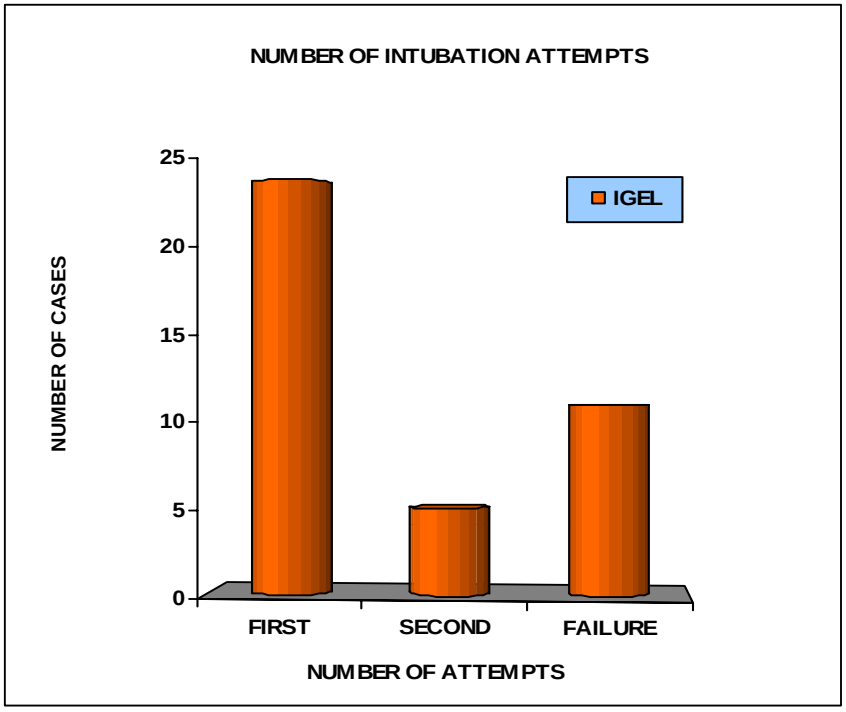

Figure 19: Number of intubation attempts for the I-GEL

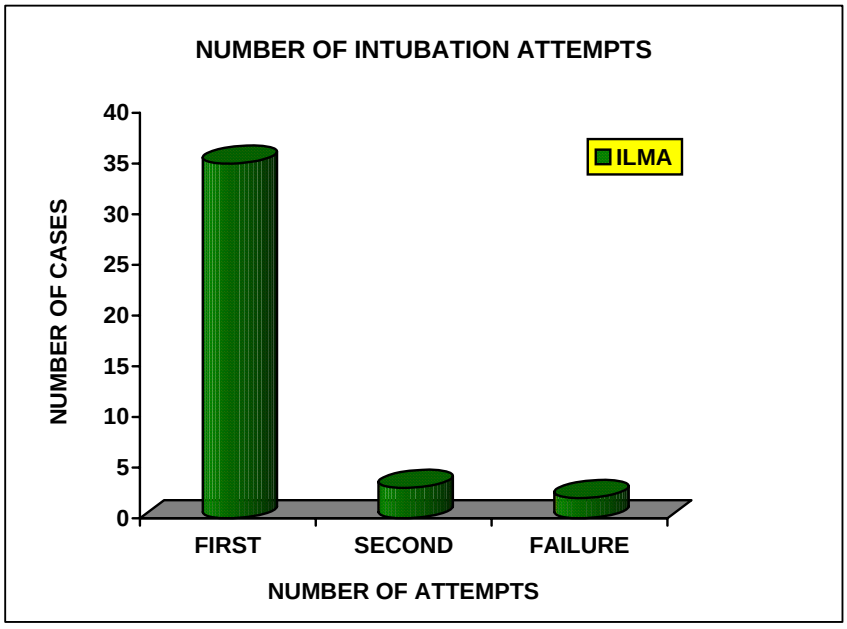

Figure 20: Number of intubation attempts for the ILMA device

SUCCESS AND FAILURE RATE FOR INTUBATION

GROUPS	INTUBATION ATTEMPT		TOTAL
	SUCCESS	FAILURE	
I-GEL	29	11	40
	72.5%	27.5%	100%
ILMA	38	2	40
	95%	5%	100%

Table 10: success and failure rate for intubation

Chi Square test with Yates' correction was applied and x^2=5.878; p=0.0153 (statistically significant)

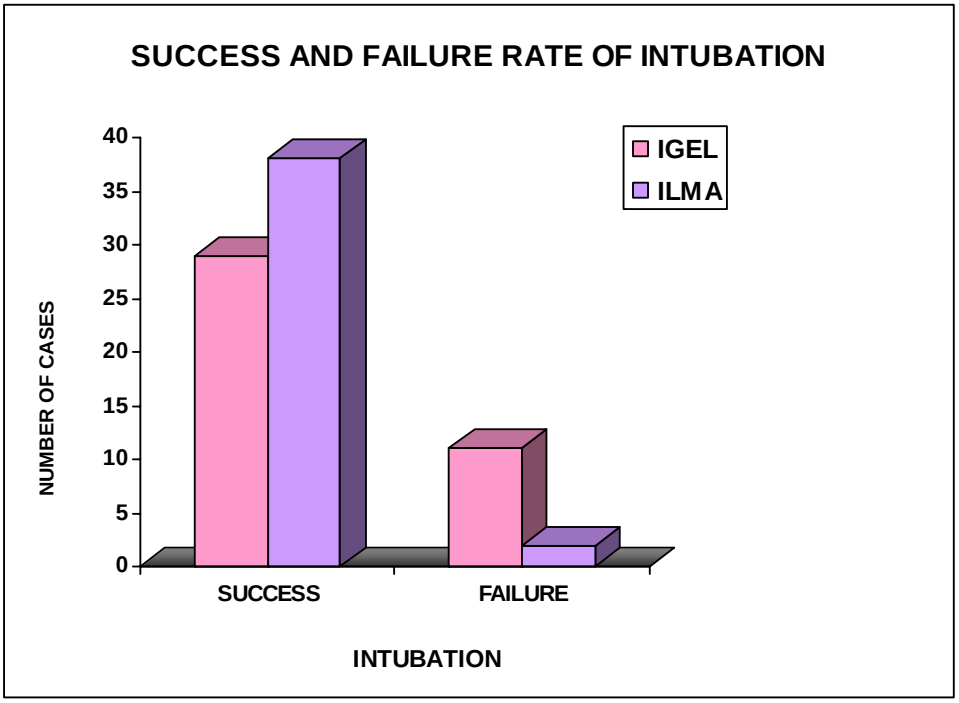

Figure 21: Success and failure rate of intubation for both I-GEL and ILMA

The overall success rate for intubation was significantly higher in ILMA group (95%) than in the I-GEL group(72.5%). We failed to intubate in eleven patients in the I-GEL group and two in the ILMA group. Subsequently they were intubated using direct laryngosopy (macintosh). Those patients who required direct laryngoscopy had a Cormack Lehane grade 1 and 2 laryngeal view and the airway anatomy appeared normal.

SUPRAGLOTTIC DEVICE REMOVAL TIME:

GROUP	N	MEAN (seconds)	S.D	Student's t-test p value
I-GEL	40	15.82	1.61	t=2.079
ILMA	40	16.55	1.50	p=0.041*****

*** Statistically significant**

Table 11: Supraglottic device removal time

The average time for I-GEL removal after intubation was significantly less than ILMA ($p<0.05$). There was no incidence of accidental extubation or tube displacement while removing the device.

TOTAL TIME FOR INTUBATION (INCLUDING DEVICE REMOVAL) IN SUCCESSFUL INTUBATION

GROUP	N	MEAN (seconds)	S.D	Student's t-test p value
I-GEL	29	49.69	6.68	t = 0.918
ILMA	38	51.13	6.13	p = 0.3621

Table 12: Total time for tracheal intubation

The mean total time for successful intubation (including the device removal) was 51.13 ± 6.13 seconds for ILMA and 49.69 ± 6.68 seconds for I-GEL. The mean total time would include the time required for supraglottic device insertion, successful tracheal intubation and supraglottic device removal. There was no statistical difference between both the groups in respect to total time required for intubation (including device removal). (P>0.05)

COMPLICATIONS:

VARIABLES	I-GEL	ILMA
Saturation <95%	0	0
Dental Trauma	0	0
Oesophageal Intubation	12	4
Laryngospasm	0	0
Mucosal Trauma	6	5

Table-13: Complications during Intubation

The incidence of oesophageal intubation was more with I-GEL in comparison with ILMA. The blood staining of the device was noted and it was an indication of mucosal trauma. Six patients in I-GEL group had mucosal trauma against five patients in ILMA group.

HEMODYNAMIC RESPONSE

The increase in systolic blood pressure, diastolic blood pressure and mean arterial pressure from the baseline values were insignificant ($p>0.05$) at one minute after tracheal intubation in both the groups. When compared among the groups, there was no significant difference in the increase in blood pressure (systolic, diastolic, mean arterial pressure) from the baseline values.

In both the groups, there was a significant ($p<0.05$) increase in heart rate at one minute after intubation from the baseline values. Among the groups, there was no significant difference between the increase in heart rate at 1 min after intubation from the baseline values.

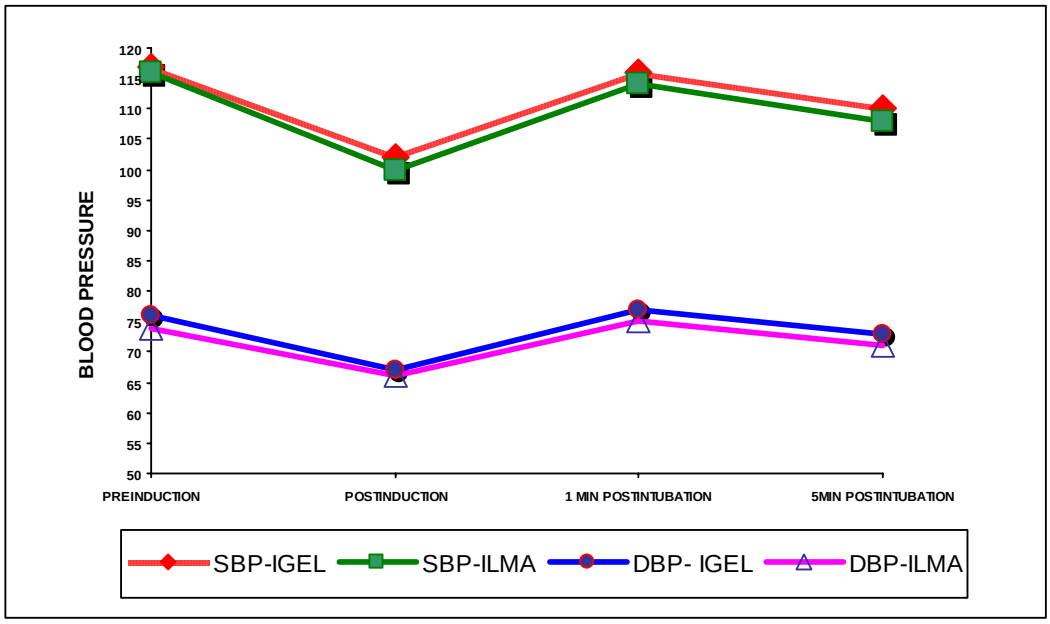

Figure 22: Changes in Systolic & Diastolic blood pressure before & after intubation in I-GEL and ILMA

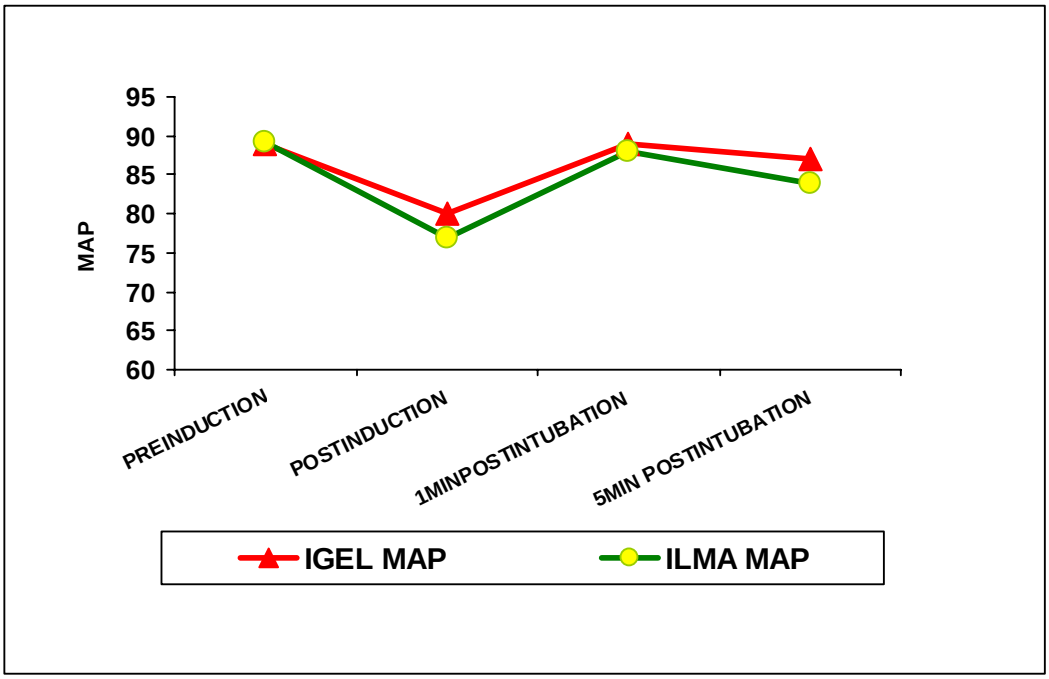

Figure 23: Changes in Mean Arterial Pressure (MAP) before and after tracheal intubation

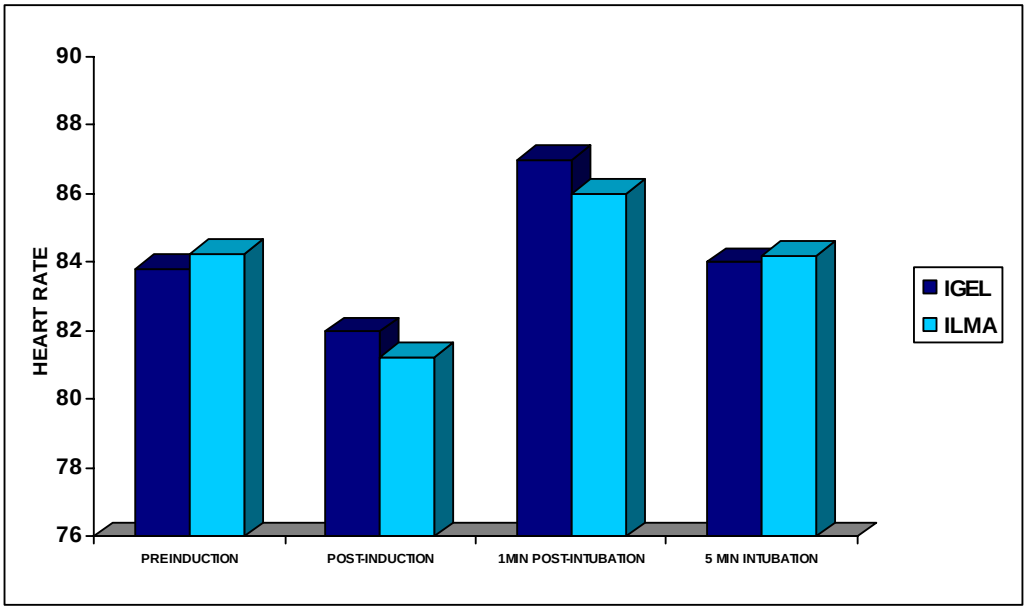

Figure 24: Variation in Heart Rate while using I-GEL and ILMA

DISCUSSION

The mean age, weight and sex ratio were comparable in both the groups. Our study showed that the I-GEL, as a ventilatory device was as effective as ILMA in maintaining the ventilation and oxygenation in the anaesthetized patients with normal airway.

The mean insertion time for supraglottic airway device was significantly less for I-GEL in comparison with ILMA. The I-GEL being an uncuffed peri-laryngeal sealer, the insertion was easy and quick. It also provided a reliable airway.

Both IGEL and ILMA were successfully inserted in all patients. The overall success rate for supraglottic airway device insertion was similar in both the groups. The result obtained with IGEL was comparable with that obtained by Gatward.J.et.al.[29] The device was inserted in first attempt in 36 patients in IGEL and 38 patients in ILMA with no significant difference.

Choosing the size of supraglottic airway device was more important as inappropriate sizing could lead to significant reduction in first attempt success rate for insertion of the device. The size of the supraglottic airway device predominantly used in the study was 4, as

majority of the patients' weight were in the range of 50- 70 kg. There were no adverse airway events recorded during placement of the supraglottic airway device.

The overall success rate of blind endotracheal intubation through ILMA with conventional PVC tubes with curvature facing downwards in patients with Mallampatti 1&2 was 95% and was significantly higher than in I-GEL (72.5%). Joo & Rose[9] reported 96.7% overall intubation success rate with reverse orientation of conventional PVC tracheal tubes through ILMA in patients with normal airway.

Kundra et.al.[19] demonstrated a 96% success rate within two intubation attempts with both Rusch PVC tubes oriented in normal direction and with silicone wire-reinforced tubes.

Michalek.et.al.[24] compared the IGEL and ILMA as a conduit for tracheal intubation in manikin and concluded that the success rate for blind tracheal intubation through ILMA was over 80% and IGEL was 63%.

The first-attempt success rate is another important performance indicator for tracheal intubation. The first attempt success rate of blind endotracheal intubation through ILMA was 87.5% similar to that

obtained by Joo.et.al [9] and through I-GEL was 60%. The first attempt success rate of blind endotracheal intubation was significantly high in the ILMA.

The curved shape of the ILMA stem which directs the tube anteriorly,[6] and the adjusting Chandy manoeuvre of ILMA used before intubation probably improved the success rate. [16]

An important factor that determines the success rate of tracheal intubation is the angle at which the tracheal tube emerges from the distal aperture of the ILMA[2] and IGEL. Tracheal intubation via an ILMA with the conventional tracheal tube inserted in reverse orientation was first described by Joo and Rose[9]. The reverse orientation of the conventional PVC endotracheal tubes through ILMA reduced the emerging angle of the tube from the ILMA (from 40º to 20º)[9,20,23] and improved the success rate of intubation even though the silicone reinforced tube was not used.

More failure in blind intubation attempts were recorded in I-GEL group. P. Michalek et.al.[24] had observed the same findings in his study. The incidence of the esophageal intubation was common with I-GEL. The reason attributed to this was the relatively straight shape of the I-

GEL stem which has a tendency to direct them posteriorly and thus increase the risk of oesophageal intubation or snaring on the arytenoids.

Joo et.al.[9] had cited that inappropriate positioning of the ILMA in relation to the glottis, as assessed by fibre-optic view, as the reason for an increase in the number of attempts and the incidence of failure to achieve tracheal intubation.

The mean time required for successful tracheal intubation in first attempt was similar in both the groups. Anitha shetty.et.al[27] had obtained similar results with ILMA.

The IGEL has a wider stem. Danha et.al[31] suggested that wider shaft of the channel and absence of bar make the tube passage ‘subjectively easy’.

The time required for the supraglottic device removal after intubation was significantly less in the I-GEL group. This uncuffed device was easier to remove with endo-tracheal tube in situ using a stabilizing rod. Sharma et.al.[13] described difficulties in removing the IGEL after intubation, but we have not noted any significant difficulties by using the silicone stabilising rod from the ILMA set.

The total time required for successful endo-tracheal intubation (including Airway insertion time, intubation time and removal of airway device) was equal in both the groups showing no statistical significant difference. The average total time for successful intubation through ILMA was 51.13 ± 6seconds and for I-GEL was 49.69 ± 6 seconds. Joo et.al[9] had similar total intubation time (from induction to tracheal intubation with exclusion of device removal) with 53.5s for blind endotracheal intubation.

The heart rate response to intubation at one and five minutes was significantly high when compared with the pre-intubation values within the group. Among the groups, the heart rate response to intubation is significantly high in the I-GEL group.

The blood pressure response to intubation recorded at one minute after intubation was insignificant when compared with the baseline values within the group. Among the groups, there was no significant difference in the blood pressure response to intubation at 1 minute after intubation from the baseline values. There was significant increase in the heart rate recorded at one minute after intubation in both the groups but when compared between the groups, there was not much of statistical significance.

There was no incidence of oxygen de-saturation in both the groups. This study had showed that both the I-GEL and ILMA effectively maintain ventilation and oxygenation. Incidence of mucosal trauma (blood staining of the device) and oesophageal intubation were more with IGEL in comparison with ILMA. There was no incidence of laryngospasm or dental trauma in both the groups.

SUMMARY

Insertion of supraglottic airway and tracheal intubation through it may be indicated where conventional laryngoscopy fails. The ILMA was specially designed for this purpose. IGEL, a relatively new device has some benefits: disposable, cheap & its wide bore facilitate direct passage of a standard size tracheal tube. It can be a useful adjunct to tracheal intubation in patients with difficult airway as documented in several case reports.[13, 14]

A prospective randomized single blind study was designed to compare the supraglottic airway devices I-GEL and ILMA as a conduit for blind endotracheal intubation in patients undergoing elective surgery under general anaesthesia

After obtaining the Institutional Ethical committee approval, eighty adult patients of ASA Physical status 1& 2 of either sex undergoing elective surgical procedures under general anaesthesia were randomly allocated into two groups, Group A: IGEL(n=40) and Group B: ILMA (n=40). Ease of tracheal intubation was assessed by the first attempt success rate, the total time required for the intubation. Ease of supraglottic device insertion was also assessed by the number of attempts and the time required for the device placement. Any complication during intubation was noted.

The study showed no significant difference between the two groups based on the demographic variables. The mean insertion time for I-GEL was significantly less than ILMA ($p<0.05$). There was no statistical difference between the two groups in number of attempts required for the placement of the supraglottic airway device.

The overall success rate, as well as the first attempt success rate for blind endotracheal intubation was high in the ILMA and were 95% and 87.5% respectively. The failure rate for blind endotracheal intubation through the supraglottic device was significantly high in the I-GEL (27.5%) with high incidence of esophageal intubation when compared to ILMA ($p<0.05$). The mean time for tracheal intubation was equal in both the groups

The time required for supraglottic device removal was significantly less for I-GEL ($p<0.05$). There was no statistically significant difference in the total time required for successful endo-tracheal intubation (including the time for airway insertion, tracheal intubation, device removal) between both the groups. Complications like oesophageal intubation and mucosal trauma were high with the IGEL.

CONCLUSION

We conclude that, based on the results of our study, I-GEL aids easy and rapid insertion as a supraglottic airway device, but when it is used as a conduit for blind endotracheal intubation, the failure rate is high as there is more incidence of oesophageal intubation. In contrary, ILMA being a gold standard device meant for intubation guide, has a high first attempt success rate for blind endotracheal intubation.

KEY TO MASTER CHART

IP NO	:	In- patient number
PS	:	American society of Anaesthesiologist Physical Status
Wt Kg	:	Weight in kilograms
MPC	:	Mallampatti Classification
ETT	:	Endotracheal tube
SBP	:	Systolic Blood pressure
DBP	:	Diastolic blood pressure
MAP	:	Mean arterial pressure
Pre- Ind	:	Pre-induction
Post-Ind	:	Post-Induction

GROUP B - ILMA

		PREINDUCTION BP			POST INDUCTION BP			1 MIN AFTER INTUBATION			5 MIN AFTER INTUBATION			HEART RATE			
SI.NO.	NAME	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	PRE-IND	POST-IND	1 MIN	5 MIN
1	GEETHA	110	80	90	96	70	79	120	76	91	120	80	93	86	80	88	88
2	SARANYA	110	80	90	96	66	76	110	74	86	108	76	87	88	82	88	86
3	SATISH	126	76	93	110	70	83	120	80	93	118	70	86	86	84	88	88
4	SENGALI	116	86	96	102	62	75	110	76	87	108	72	84	87	88	89	89
5	AGIVAN	126	70	89	100	60	73	116	70	85	114	60	78	90	84	89	92
6	RABITA	118	70	86	110	60	77	110	70	83	110	68	82	90	86	88	84
7	EMAROSE	120	80	93	96	66	76	116	76	89	106	70	82	88	84	89	88
8	AVINASH	120	80	93	90	66	74	116	74	88	110	68	82	80	70	78	82
9	GOPI	116	80	92	98	64	75	120	76	91	112	72	85	88	80	88	86
10	MARY	126	80	95	106	70	82	118	76	90	116	70	85	80	76	84	82
11	LAKSHMI	128	80	96	106	70	82	116	78	91	110	72	85	80	76	84	82
12	RAMYA	106	70	82	90	60	70	110	66	81	100	70	80	80	74	83	80
13	RADHIKA	116	80	92	100	70	80	118	76	90	112	70	84	86	80	87	88
14	RADHA	116	70	85	96	70	79	114	76	89	112	70	84	84	80	85	86
15	RAJA	118	74	89	96	66	76	118	76	90	110	70	83	80	76	86	86
16	CHITRA	120	80	93	100	70	80	110	76	87	116	74	88	86	84	88	86
17	UMA SHANKAR	118	70	86	100	70	80	120	76	91	110	74	86	86	78	86	84
18	SHANTHI	122	76	91	98	70	79	116	76	89	108	66	80	86	80	88	84
19	MOHAN	126	80	95	100	76	84	110	82	91	112	70	84	84	78	85	82
20	ARUL RAJ	106	68	81	94	60	71	110	68	82	106	66	79	84	76	82	80
21	SHANKAR	126	80	95	100	70	80	116	80	92	114	80	91	89	84	88	88
22	DHANASEKAR	120	78	92	100	70	80	116	80	92	110	76	87	90	86	88	84
23	PRIYA	110	70	83	96	62	73	110	72	85	106	70	82	86	87	89	88
24	RANI	116	70	85	100	74	83	118	78	91	112	76	88	86	88	90	87
25	SELVI	117	70	86	98	68	78	116	70	85	112	68	83	84	87	86	86
26	RUKUMANI	116	68	84	96	69	78	110	72	85	118	76	90	79	82	85	82
27	ESWARI	110	76	87	96	67	77	110	78	89	106	72	83	72	76	78	75
28	JAYA PRADHA	120	80	93	106	72	83	116	80	92	114	76	89	86	84	89	88
29	ARAVINDH	116	70	85	100	60	73	118	76	90	112	70	84	80	72	79	76
30	SHANTHA	112	70	84	96	68	77	110	76	87	108	72	84	82	80	88	86
31	GANESH	126	76	93	106	70	82	116	76	89	112	70	84	84	86	88	82
32	SARANYA	116	80	92	98	66	77	118	76	90	108	70	83	86	80	86	82
33	SHANTHI	110	76	87	96	68	77	110	72	85	104	80	88	90	82	92	88
34	ASHOK KUMAR	120	74	89	98	68	78	118	70	86	114	76	89	87	88	90	82
35	KALAIVANI	120	76	91	104	76	85	126	80	95	120	88	99	78	80	84	84
36	MARRIAPPAN	105	74	84	95	60	72	110	76	87	106	72	83	87	89	88	84
37	SHANTINI	100	70	80	94	66	75	106	76	86	104	67	79	74	79	82	80
38	RUKUMANI	120	80	93	90	70	77	126	84	98	110	70	83	94	86	90	89
39	BAGYALAKSHMI	118	70	86	100	66	77	120	76	91	110	70	83	84	80	88	84
40	SENTHIL GANESH	108	76	87	97	64	75	110	70	83	107	70	82	74	78	82	79

GROUP A - IGEL

		PREINDUCTION BP			POST INDUCTION BP			1 MIN AFTER INTUBATION			5 MIN AFTER INTUBATION			HEART RATE			
Sl.NO.	NAME	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	PRE-IND	POST-IND	1 MIN	5 MIN
1	AMMU	120	84	96	106	70	82	120	80	93	124	80	95	80	76	86	84
2	KANAGAJOTHI	116	76	89	98	68	78	110	80	90	100	70	80	86	88	89	94
3	DEVI	118	82	94	100	66	77	116	80	92	110	70	83	80	82	88	88
4	LAKSHMI	118	78	91	98	68	78	116	80	92	114	72	86	87	88	90	88
5	KADHIRAVAN	110	70	83	96	66	76	106	70	82	110	76	87	84	86	88	86
6	JERRINA	120	78	92	110	68	82	124	76	92	118	70	86	87	89	90	88
7	MUMTAJ	116	80	92	108	68	81	128	86	100	120	80	93	84	86	89	82
8	SABINA	120	82	95	100	70	80	120	80	93	122	80	94	82	84	84	88
9	RUKUMANI	120	86	97	108	70	83	120	80	93	118	80	93	80	74	82	80
10	BABU	106	72	83	90	60	70	108	70	83	104	70	81	76	78	80	78
11	SUGANTHI	124	76	92	104	70	81	120	80	93	126	66	86	84	82	86	84
12	MANI	112	70	84	98	68	78	116	74	88	110	70	83	88	86	90	88
13	BALAJI	116	76	89	100	70	80	120	80	93	122	76	91	80	82	84	84
14	VIDYA	118	78	91	96	70	79	110	80	90	112	82	92	89	90	92	88
15	RADHIKA	116	80	92	98	60	73	118	70	86	116	72	87	88	84	88	86
16	LAKSHMI	120	78	92	100	70	80	120	80	93	118	70	86	88	86	89	90
17	RAJASEKAR	114	76	89	110	72	85	117	80	92	120	80	93	88	90	91	90
18	RAJALAKSHMI	124	76	92	100	70	80	120	84	96	116	70	85	84	83	89	90
19	DAMODHARAN	118	78	91	98	60	73	110	70	83	112	72	85	86	84	87	90
20	VIMALA	120	76	91	98	68	78	116	70	85	118	70	86	81	85	88	94
21	SANGEETHA	116	68	84	99	66	77	112	68	83	118	74	89	80	80	87	90
22	MURUGAN	116	68	84	90	60	70	110	70	83	114	68	83	82	86	87	90
23	VISWANATHAN	118	70	86	97	67	77	114	67	83	116	76	89	82	88	89	86
24	CHINNAMMAAL	114	74	87	96	70	79	126	86	99	120	68	85	86	84	85	88
25	PUROSHOTHAMAN	108	68	81	90	60	70	110	70	83	106	70	82	86	84	88	87
26	POONGODI	108	70	83	98	68	78	116	80	92	106	70	82	81	78	85	85
27	AMEENA	114	76	89	98	66	77	106	78	87	124	80	95	82	84	86	82
28	ANNAPOORANI	120	76	91	100	60	73	116	70	85	124	72	89	86	84	88	94
29	CHINNASAMY	121	78	92	110	70	83	120	76	91	116	74	88	76	75	80	84
30	MANI	118	70	86	100	70	80	120	80	93	114	72	86	84	82	88	86
31	SANJEEV	130	89	103	100	66	77	118	76	90	126	78	94	80	84	96	94
32	NALAYINI	120	76	91	98	66	77	110	70	83	118	70	86	86	87	89	84
33	SHANKARI	116	70	85	120	76	91	108	70	83	112	72	85	86	88	90	86
34	MUNIYAMMAL	128	76	93	116	70	85	126	80	95	124	70	88	84	84	88	86
35	PARAMESWARAN	126	90	102	110	70	83	120	80	93	128	96	107	90	89	106	99
36	PUNITHA	128	86	100	100	60	73	118	70	86	120	76	91	84	86	98	92
37	PRASAD	122	86	98	106	70	82	124	86	99	118	76	90	84	86	92	88
38	RAJALAKSHMI	120	76	91	100	70	80	118	68	85	116	68	84	84	86	94	92
39	PALANISAMY	128	86	100	100	76	84	124	84	97	126	74	91	82	78	98	91
40	MEENABAI	124	76	92	96	68	77	108	70	83	118	76	90	86	84	88	82

PROFORMA

Name :

Group assigned :

Age / Sex :

IP No :

Diagnosis :

Surgery :

ASA Status : Associated medical illness :

Weight :

Airway : MPC

Last Oral intake :

Premedication :

Shifted to theatre :

Monitors –baseline values: HR :

SpO2 :

BP :

IV access secured :

Preoxygenation : 100% oxygen for 3 min

Induction : Propofol mg.

Relaxant : Inj Atracrurium mg

SUPRAGLOTTIC DEVICE:

Size :

Insertion time (seconds) :

Number of attempts :

Tracheal Intubation

Endotracheal tube size :

Time (seconds) :

Intubation Attempts

One (Without Maneuver) :

One (With Maneuver) :

Two :

TIME required for the removal of supraglottic device :

Total time required for tracheal intubation :

(including supraglottic device insertion and removal)

COMPLICATIONS :

Saturation <95 :

Dental trauma :

Esophageal intubation :

Laryngospasm :

Mucosal trauma :

Hemodynamic parameters :

1. Pre induction Blood pressure -
2. Post induction Blood pressure -
3. BP 1 min after intubation-
4. BP 5 min after intubation-

1. Pre Induction Heart Rate -
2 .Post induction Heart Rate-
3. HR 1 min after intubation-
4. HR 5 min after intubation-

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